16. 510(k) Summary

Date Prepared July 26, 1999

Submitter

Address: Boston Scientific Corporation
Plymouth Technology Center
5905 Nathan Lane
Minneapolis, MN 55442

Phone: (612) 694-5500
Fax: (612) 694-5858

Contact Person Ronald W. Bennett
Regulatory Affairs Project Manager

Device Name and Classification

Trade Name: WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System

Common Name: Tracheal Endoprosthesis

Classification: Class III

Predicate Devices WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System - K964121

Device Description

The WALLSTENT® Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. Smaller diameter models may utilize a radiopaque core. The prosthesis is a braided wire structure which may be covered with an elastomeric polymer in selected models. The outward radial force along with the ends of the device serve to stabilize the prosthesis after implanted. The stent's purpose is to increase or maintain the inner lumenal diameter of the tracheobronchial passage.

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly that constrains the prosthesis until it is released in a controlled manner. The release of the stent is accomplished by retracting the outer sheath. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

Indication

The WALLSTENT® Tracheobronchial Endoprosthesis is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Technological Characteristics

The purpose of this 510(k) is to allow an alternate delivery system. Compared to the present Unistep™ Plus Delivery System (K964121), this version of the Unistep™ Plus delivery system has a reduced profile, that is smaller French size.

The alternate delivery system can be found substantially equivalent based on the results of *in vitro* testing that demonstrates the deployment forces and handling characteristics are comparable to the current delivery systems.

Summary

In summary Boston Scientific Corporation has demonstrated that the WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery with reduced profile for the delivery system is substantially equivalent based on design, test results, and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 1999

Mr. Ronald W. Bennett
Regulatory Affairs Project Manager
Boston Scientific
Plymouth Technology Center
5905 Nathan Lane
Plymouth, Minnesota 55442-1656

Re: K992510
Trade Name: WALLSTENT® Tracheobronchial Endoprosthesis
Regulatory Class: III
Product Code: JCT
Dated: October 31, 1999
Received: November 3, 1999

Dear Mr. Bennett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992510

510(k) Number (if known):

Device Name: **WALLSTENT® Tracheobronchial Endoprosthesis**

Indications for Use:

The WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992510

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)